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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,294	05/25/2001	Chang Yi Wang	1151-4167	5186

7590 10/21/2002

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EXAMINER

*Andres Janet L*

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/21/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/865,294	WANG, CHANG YI
	<b>Examiner</b>	<b>Art Unit</b>
	Janet L Andres	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-80 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-80 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Election/Restrictions***

On consideration, the restriction requirement of paper no. 5 is withdrawn. A requirement for an election of species follows:

This application contains claims directed to the following patentably distinct species of peptide immunogen:

The species comprise

I. a T helper epitope selected from a group consisting of :

SEQ ID Nos 1-64

II. a fragment of A $\beta$ <sub>1-42</sub> peptide selected from a group consisting of:

- a) SEQ ID NO: 65
- b) SEQ ID NO: 66
- c) SEQ ID NO: 67
- d) SEQ ID NO: 68
- e) SEQ ID NO: 69

III. a linker selected from a group consisting of:

- a) an amino acid
- b) Gly-Gly
- c) ( $\alpha$ ,  $\epsilon$ -N)-Lys
- d) SEQ ID NO: 73

While each of the epitopes serves a common purpose, they are different proteins with different characteristics and a different status in the art. A search for one would not reveal art relevant to another, and successful use of one would not render successful use of another obvious. Peptides comprising these sequences and thus methods using them are patentably distinct.

While, as indicated in Table 3 of Applicant's disclosure, the fragments of  $\text{A}\beta_{1-42}$  peptide are nested fragments of different lengths, one fragment does not render another obvious. Art relevant for one fragment, absent a clear motivation to alter the length of that fragment, would not be relevant to another. Further, successful use of one fragment would not render successful use of another obvious. Thus each of these fragments is patentably distinct.

While each of the linkers serves a common purpose, they are different molecules with different characteristics, and one would not render another obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of immunogen, comprising a single disclosed species of epitope selected from GROUP I, of  $\text{A}\beta_{1-42}$  peptide selected from GROUP II, and of linker selected from GROUP III for prosecution on the merits to which the claims shall be restricted if **no generic claim is finally held to be allowable**. Currently, claims 1, 2, 5, 12, 21, 22, 25, 32, 41, 42, 45, 52, 61, 62, 65, and 72 are generic. Applicant is also required to identify the claims that read on the elected species including any claims subsequently added. Further, Applicant is requested to specify the SEQ ID Nos: of those peptides that are within the elected species, so that the claimed invention can be correctly

examined. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

**Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.** If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

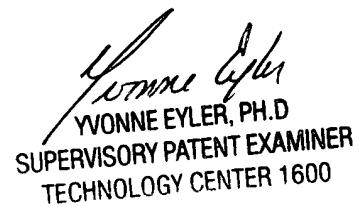
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
October 18, 2002



YONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600